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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,581	10/23/2001	John H. Stevens	HRT-287	4692

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EXAMINER	
ISABELLA, DAVID J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,581	STEVENS, JOHN H.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-21,23-32 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,23-32,42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892).
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/02; 5/03; 9/03; 3/04; 9/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of the Claims

Currently claims 15-21,23-32,42-44 are pending. Applicant amended claim 15 to further define the sleeve as having an outside surface with the ring attached to the outside surface of the sleeve and that the sleeve is not everted. All other claims remain unchanged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-21,23-32,42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek [3657744].

Ersek discloses a valve [45] for implantation within a mammal, comprising a fexible sleeve [portion of valve forming rim 45] having a proximal end, and a distal end and an outside surface; at least one cusp [46] configured; to permit blood flow through at least one cusp in a single direction; at least one ring [16] attached to the outside surface of the sleeve, the at least one rinq being attached to a portion of the sleeve that is not everted; and at least one fastener extending in a direction radially outward with respect to the sleeve. See figure 8

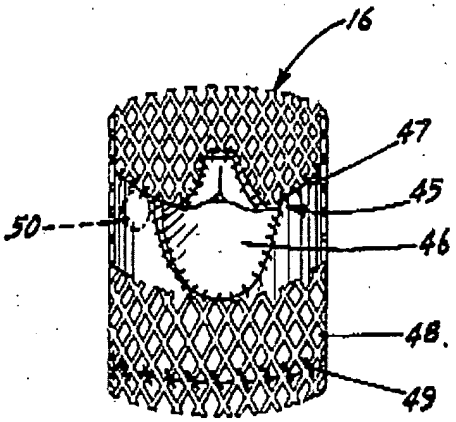

FIG. 8

In FIG. 8 there is shown an aortic heart valve 45 in place in a fixation sleeve 16. The rim of valve 45 adjacent the cusps 46 is attached by sutures 47 to the sleeve near one end. A segment of the donor aorta 48 is attached by sutures 49 near the other end of sleeve 16. The opening 50 in the aorta wall for a coronary artery can be matched with the corresponding opening in the wall of the donee aorta.

The expanded metal sheeting is desirably not flattened prior to forming into a sleeve. The result, as seen schematically in FIG. 5, is that the ribbon-like portions 22 of the sleeve extend angularly relative to the perimeter of the sleeve providing a multitude of narrow projecting edges which embed themselves into the tissue wall upon expansion of the sleeve. After being

Claims 16-20, see the three cusps configuration of Ersek. The valve is designed such that the three cusps have edges that mate along adjacent edges such that the cusps open distally with respect to blood flow and are configured to close to prevent back flow of blood.

Claim 21, see attachment of the ring to the valve in figures 8 and 9.

Claims 23 and 24, see column 2.

The tubular sleeve 16 is made of deformable material such that it retains its expanded dimensions after expansion in place. It is formed from a non-toxic material compatible with blood and other body fluids, such as stainless steel. Its walls

Claims 25 and 26, see column 3, lines 1+.

Claim 29, an expander tool is used to expand the ring and therefor the valve is capable to be expanded by a balloon expander tool.

Claims 42-44, see column 3, lines 1+.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-32,42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peale or Rygg (4218782) in view Sakura [4214587] and/or Ersek [3657744]. The device of Peale may be inserted into the natural conduit but must rely on strict adherence to sizing diameters to match the diameter of the natural conduit. Sakura, Jr allows for direct attachment of the valve of Peale to the natural conduit without strict

adherence to matching diameters thus alleviating the need for frictional fit. Moreover the spring of Sakura, Jr allows the attaching vessel to pulsate in a fashion similar to that of the natural conduit. It would have been obvious to one with ordinary skill in the ad to attach the vessel of Peale to the natural conduit via a compressible spring member as shown by Sakura, Jr. With respect to claim 29, clearly the spring is capable of being balloon expandable as broadly claimed. Ersek teaches a means for attaching the ring to the valve without everting the valve. To attach the ring of Sakura to the sleeve with out everting the sleeve would have been obvious to one with ordinary skill in the art from the teachings of Ersek as being obvious equivalents.

The device of Rygg includes a valve for implantation comprising a flexible sleeve having proximal and distal ends; and at least one cusp configured to permit blood flow through the sleeve in a single direction and one ring attached to the sleeve. While the device of Rygg may be inserted into the natural conduit, the device is sutured to the adjacent tissues of the natural conduit. .Ersek and Sakura teaches the combination of tubular vascular device comprising a cylindrical elements formed with outwardly extending fasting elements for attaching a vessel to a natural conduit. Ersek allows for direct attachment of the sleeve/valve to the natural conduit without strict adherence to matching diameters and the complexities surrounding the use of sutures. Moreover the spring/fastening combination of Sakura and Ersek will allows the attaching vessel to pulsate in a fashion similar to that of the natural conduit. It would have been obvious to one with ordinary skill in the art to attach the sleeve/valve of Rygg to the natural conduit via a compressible spring member as shown by Ersek and/or Sakura. With respect to

claim 29, Lazarus teaches the use of a balloon to expand the radially resilient spring/fastening elements to attach the sleeve to the natural conduit.

Likewise, Sakura, Jr teaches a anastomosis device comprising a cylindrical radially resilient spring formed with outwardly extending fasting elements for attaching a vessel to a natural conduit. It would have been obvious to one with ordinary skill in the art to attach the sleeve/valve of Rygg to the natural conduit via a compressible spring member as shown by Sakura, Jr.

Claims 16,17,18,19,20, see figures 11 and 12 of Rygg.

Claim 21, see mounting ring located at the proximal and distal ends of the sleeve of Lazarus.

Claim 22, see combination of Sakura, Jr.

Claims 23-28, see Rygg as modified by either of Lazarus or Sakura, Jr.

Claim 29-32, see expandable combination as taught by Rygg and Lazarus.

Claims 42-44, see fasteners of Lazarus.

Response to Arguments

Applicant's arguments with respect to claim 15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
4/24/2006